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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	7133.US.O1	5085

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EXAMINER

OLSEN, KAJ K

ART UNIT PAPER NUMBER

1753

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,695

Applicant(s)

PIERCE ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-16,18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-16, 18, 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The examiner has withdrawn the 102 rejection over Gilmartin (USP 5,795,453) in view of the amendment to claims 1 and 16 specifying a dehydrogenase enzyme, which Gilmartin does not disclose (however, see the new 103 rejection below).
2. The examiner has also withdrawn the 102 rejections over Feldman (USP 6,299,757) and Hughes (USP 6,129,823) in view of the deletion of the “substrate for an enzyme” from claims 1 and 16. The use of these references for the 103 rejections can be found below.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 3, 5-16, 18 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman and Gilmartin.
5. Feldman discloses a biosensor (col. 1, ll. 13-14) having: (a) an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); (c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and (d) at least one reagent incorporated in the working electrode (col. 21 , ll. 28- 31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15,

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ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38).

Feldman does not disclose placing at least one of the enzyme or mediator and the enzyme into the first conductive track. Gilmartin discloses that the enzyme need not be placed over the electrode and conductive track itself, but that the enzyme and the mediator could be incorporated into the ink itself. See col. 10, ll. 49-52. This would appear to obviate the need for multiple coating steps (i.e. a separate coating of the enzyme layer would not be needed). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gilmartin for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode. With respect to the enzyme and mediator being incorporated into the conductive track itself, Gilmartin would appear to utilize its ink for the deposition of both the working area of the electrodes (area C on fig. 1) and the connecting strip portion (area A of fig. 1). See also the discussion from the non-final office action of 6-29-2005.

6. With respect to the various dependent claim limitations, see the discussion of Feldman and these limitations in the office action of 6-29-2005.

7. Claims 1, 3, 10, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes in view of Gilmartin and Feldman.

8. Hughes discloses a biosensor (col. 1, ll. 5-6) having (a) an electrode support (col. 2, l. 10 and Fig. 1, 1); (b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 2, ll. 11-12 and Fig. 1, 4, 5 and 5a); (c) a first conductive track leading from the working

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electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1 , 2)., and (d) at least one reagent incorporated in the working electrode (col. 4, ll. 28- 29) comprising an enzyme and a mediator (col. 4, ll. 40-42). Hughes does not disclose placing at least one of the enzyme or mediator and the enzyme into the first conductive track or the use of a dehydrogenase enzyme. Gilmartin discloses that the enzyme need not be placed over the electrode and conductive track itself, but that the enzyme and the mediator could be incorporated into the ink itself. See col. 10, ll. 49-52. This would appear to obviate the need for multiple coating steps (i.e. a separate coating of the enzyme layer would not be needed). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gilmartin for the biosensor of Hughes so as to obviate the need for multiple coating steps for the electrode. With respect to the enzyme and mediator being incorporated into the conductive track itself, Gilmartin would appear to utilize its ink for the deposition of both the working area of the electrodes (area C on fig. 1) and the connecting strip portion (area A of fig. 1). See also the discussion from the non-final office action of 6-29-2005. With respect to the use of a dehydrogenase enzyme, it doesn't appear that Hughes placed any criticality on the use of glucose oxidase, but rather stated that the enzyme was the preferred choice. See col. 4, ll. 42-46. The previously relied on Feldman disclosed that biosensors can be configured to monitor glucose by relying on either glucose oxidase or glucose dehydrogenase. See col. 24, ll. 24-27. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Feldman for the biosensor of Hughes and

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Gilmartin because the substitution of one known enzyme for another known and analogous enzyme requires only routine skill in the art.

9. With respect to the various dependent claim limitations, see the discussion of Hughes and these limitations in the office action of 6-29-2005.

10. Claims 1, 3, 5, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilmartin in view of Feldman.

11. In previous office actions, it was set forth how Gilmartin anticipated these claims. See the office actions of 6-29-2005 and 1-6-2006. The claims have been amended to specify the use of a dehydrogenase enzyme, which Gilmartin does not explicitly disclose. However, Gilmartin is drawn to a sensor for a myriad of analytes (col. 17, l. 28 through col. 18, l. 31) and only discloses the preferred use of an oxidase enzyme as the redox enzyme (col. 9, ll. 57-61). The previously relied on Feldman disclosed that biosensors can be configured to monitor glucose by relying on either glucose oxidase or glucose dehydrogenase. See col. 24, ll. 24-27. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Feldman for the biosensor of Gilmartin because the substitution of one known enzyme/mediator combination for another known and analogous enzyme/mediator combination requires only routine skill in the art.

12. With respect to the various dependent claim limitations, see the discussion of Gilmartin and these limitations in the office action of 6-29-2005.

Response to Arguments

13. Applicant's arguments filed 5-8-2006 have been fully considered but they are not persuasive. Applicant's arguments concerning the 102 rejections over Gilmartin are moot in view of the new grounds of rejection.

14. With respect to the rejection relying on Feldman, applicant urges that Feldman does not disclose the use of an enzyme in a conductive track or in an electrical contact of the biosensor. However, that is the purpose of the teaching of the secondary teaching of Gilmartin, which does teach incorporating the enzyme into the ink that is to become the electrode and conductive track for the biosensor. With respect to the use of Gilmartin, applicant urges that it doesn't teach the incorporation of a dehydrogenase enzyme. However, Feldman already disclosed that the enzyme could be either an oxidase or a dehydrogenase. For the rejection of Feldman in view of Gilmartin, the examiner is relying on the teaching of Gilmartin solely for the teaching that the mediator and/or enzyme could be incorporated into the electrode ink to arrive at the desired enzyme/mediator/electrode function. More specifically, Gilmartin taught that the enzyme could be deposited as a layer over the electrode (col. 9, ll. 42-46) (like Feldman utilizes) or could be incorporated into the ink containing the electrode material (col. 10, ll. 49-52). There is nothing enzyme specific about the use of this teaching here. If Gilmartin were able to successfully incorporate its enzyme/mediator combination into the electrode ink, one possessing ordinary skill in the art would recognize that other known enzyme/mediator combinations could also have been utilized. In fact, Gilmartin states that "[a]ny of the suitable enzymes mentioned herein and *known in the art for redox reactions* can be used in such electrodes" (emphasis added) (col. 10, ll. 55-57). Dehydrogenase enzymes are clearly well known in the art for redox reactions as

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evidenced by the teaching of Feldman. Moreover, the examiner would point out that applicant does not appear to set forth any criticality to the enzyme being utilized. See the original claim 4 and p. 17, ll. 4-17.

15. Applicant's arguments for Hughes are similarly unpersuasive. The fact that Hughes only deposited the reagents over the electrodes only ignores that the examiner was relying on the teaching of Gilmartin for the teaching of adding the reagents to the entire ink utilized for the electrodes and conductive tracks. The arguments concerning the use of dehydrogenase are moot in view of the further teaching of Feldman above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 18, 2006



KAJ K. OLSEN
PRIMARY EXAMINER